DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 417 and 422

[HCFA-1030-FC]

RIN 0938-AI29

Medicare Program; Medicare+Choice Program

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period responds to comments on the June 26, 1998 interim final rule that implemented the Medicare+Choice (M+C) program and makes revisions to those regulations where warranted. We also are making revisions to the regulations that are necessary to reflect the changes to the M+C program resulting from the Balanced Budget Refinement Act of 1999 (BBRA). Revisions to the regulations reflecting changes in the law made by the BBRA are subject to public comment. Issues discussed in this rule include eligibility, election, and enrollment policies; marketing requirements; access requirements; service area and benefit policy; quality improvement standards; payment rates, risk adjustment methodology, and encounter data submission; provider participation rules; beneficiary appeals and grievances; contractual requirements; and preemption of State law by Federal law.

This final rule also addresses comments on the interim final rule published on December 2, 1997, which implemented user fees for section 1876 risk contractors for 1998, and formed the basis for the M+C user fee provisions in the June 26, 1998 interim final rule, and the provider-sponsored organization (PSO) interim final rule published April 14, 1998.

DATES: Effective date: This final rule is effective **[OFR: Please insert date 30 days after the date of publication in the Federal Register]**.

Comment period: Comments on provisions reflecting provisions of the Balanced Budget Refinement Act of 1999 will be considered if received at the appropriate address, as provided below, no later than **[OFR: Please insert date 60 days after the date of publication in the Federal Register]**. We will not consider comments concerning regulatory provisions that remain unchanged or that are revised in this final rule based on previous public comment.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY:

Health Care Financing Administration,

Department of Health and Human Services,

Attention: HCFA-1030-FC,

P.O. Box 8013,

Baltimore, MD 21244-8013.

Since comments must be received by the date specified above, please allow sufficient time for mailed comments to be received timely in the event of delivery delays.

If you prefer, you may deliver by courier, your written comments (one original and three copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW,
Washington, DC 20201; or

C5-14-03, Central Building,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Comments mailed to the two above addresses may be delayed and received too late to be considered. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1030-FC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department’s offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone (202) 690-7890).

For comments that relate to information collection requirements, see section IV of the Supplementary Information.

FOR FURTHER INFORMATION CONTACT:

Marty Abeln (410) 786-1032 (for issues related to user fees, service area, point-of-service option, PSOs, and intermediate sanctions).

Wendy Burger (410) 786-1566 and Lynn Orlosky (410) 786-5930 (for issues related to eligibility, elections, and enrollment).

Carol Barnes (410) 786-5496 (for issues related to continuation areas and marketing).

Anne Manley (410) 786-1096 (for issues related to emergency and urgently needed services, provider participation rules, and Federal preemption).

Eileen Zerhusen (410) 786-7803 (for issues related to post-stabilization care).

Tony Hausner (410) 786-1093 (for issues related to access, discrimination, and physician incentive rules).

Amy Chapper (410) 786-0367 (for issues related to information disclosure and confidentiality).

Brian Agnew (410) 786-5964 (for issues related to quality assurance and accreditation).

Al D'Alberto (410) 786-1100 (for issues related to payments, premiums, and ACRs).

James Hart (410) 786-4474 (for issues related to risk adjustment and encounter data).

Chris Eisenberg (410) 786-5509 (for issues related to contracts and contract appeals).

Michele Edmondson (410) 786-6478 (for issues related to beneficiary appeals).

Anita Heygster (410) 786-4486 (for issues related to M+C private fee-for-service plans).

Cindy Mason (410) 786-6680 (for issues related to M+C MSA plans).

SUPPLEMENTARY INFORMATION:

For the convenience of the reader, we are providing a complete outline of this final rule, including a topical listing of the major areas raised by the comments, along with numerical regulatory citations.

a. Definitions

b. Enforcement of Emergency Requirements

c. Access to Emergency and Urgently Needed Services

d. Post-Stabilization Care Services

3. Service Area Requirements (§§422.2, 422.100)

4. Benefits (§§422.2, 422.100, 422.101, 422.106)

5. Special Rules for Screening Mammography, Influenza Vaccine, and Pneumococcal Vaccine (§422.100(h))

6. Special Rules for Point-of-Service (POS) Option (§422.105)

7. Medicare Secondary Payer (MSP) Procedures (§422.108)

8. National Coverage Determinations (§422.109)

9. Discrimination Against Beneficiaries Prohibited (§422.110)

10. Disclosure Requirements (§422.111)

11. General Access Requirements (§422.112)

a. Introduction

b. Provider Network (§422.112(a)(1))

c. Primary Care Providers (PCP) Panels (§422.112(a)(2))

d. Specialty Care (§422.112(a)(3))

e. Serious Medical Conditions (§422.112(a)(4))

f. Written Standards (§422.112(a)(7))

g. Cultural Considerations (§422.112(a)(9))

12. Confidentiality and Accuracy of Enrollee Records (§422.118)

13. Information on Advance Directives (§422.128)

D. Quality Assurance (Subpart D)

1. Overview

2. Quality Assessment and Performance Improvement Requirements (§422.152)

3. External Review (§422.154)

4. Deemed Compliance Based on Accreditation (§422.156)

5. Accreditation Organizations (§422.157)

6. Procedures for Approval of Accreditation as a Basis for Deeming Compliance (§422.158)

E. Relationships With Providers (Subpart E)

1. Provider Participation Procedures (§§422.202(a), and 422.204(c))

2. Consultation Requirements (§422.202(b))

3. Treatment of Subcontracted Networks (§422.202(c))

4. Provider Antidiscrimination (§§422.100(j), 422.204(b), and new §422.205)

5. Provider Credentialing (§422.204(a))

6. Prohibition on Interference with Health Care Professionals' Communication with Enrollees (§422.206)

7. Physician Incentive Plans (§§422.208 and 422.210)

8. Special Rules for Services Furnished by Noncontract Providers (§422.214)

9. Exclusion of Services Furnished Under a Private Contract (§422.220)

10. M+C Plans and the Physician Referral Prohibition

F. Payments to M+C Organizations (Subpart F)

1. General Provisions (§422.250)

2. Risk Adjustment and Encounter Data (§422.256 through §422.258)

3. Special Rules for Hospice Care (§422.266)

G. Premiums and Cost-Sharing (Subpart G)

1. General Provisions (§422.300)

2. Rules Governing Premiums and Cost-Sharing (§422.304)

3. Submission Requirements of the Proposed Premiums and Related Information (§422.306)

4. Limits on Premiums and Cost-Sharing Amounts (§422.308)

5. Incorrect Collections of Premiums and Cost-Sharing Amounts (§422.309)

6. ACR Approval Process (§422.310)

7. Requirement for Additional Benefits (§422.312)

H. Provider-Sponsored Organizations (Subpart H)

I. Organization Compliance With State Law and Preemption by Federal Law (Subpart I)

1. State Licensure and Scope of Licensure (§422.400)

2. Federal Preemption of State Law (§422.402)

a. General Preemption (§422.402(a))

b. Specific Preemption (§422.402(b))

3. Prohibition on State Premium Taxes (§422.404)

4. Medigap

J. (Subpart J--Reserved)

K. Contracts with M+C Organizations (Subpart K)

1. Definitions (§422.500)

2. National Contracting (§422.501)

3. Compliance Plan (§422.501(b)(3)(vi))

4. Access to Facilities and Records (§422.502(e))

5. Disclosure of Information (§422.502(f)(2)(v))

6. Beneficiary Financial Protection (§422.502(g))

7. Requirements of Other Laws and Regulations (§422.502(h))

8. Contracting/Subcontracting Issues (§422.502(i))

9. Certification of Data that Determine Payment/Certification of Accuracy of ACR (§422.502(l))

10. Effective Date and Term of Contract (§422.504)

11. Nonrenewal of M+C Contracts (§422.506)

12. Provider Prior Notification and Disclosure (§§422.506(a), 422.508, 422.510(b), and 422.512)

13. Mutual Termination of a Contract (§422.508)

14. Termination of Contract by HCFA (§422.510)

15. Minimum Enrollment Requirements (§422.514)

16. Reporting Requirements (§422.516)

17. Prompt Payment by M+C Organization (§422.520)

L. Effect of Change of Ownership or Leasing of Facilities During Term of Contract (Subpart L)

M. Grievances, Organization Determinations, and Appeals (Subpart M)

1. Background and General Provisions (§§422.560, 422.561, and 422.562)

2. Grievance Procedures (§422.564)

3. Organization Determinations (§§422.566 through 422.576)

4. Reconsiderations by an M+C Organization or Independent Review Entity (§§422.578 through 422.616)

5. Effectuation of a Reconsidered Determination (§422.618)

6. Notification of Noncoverage in Inpatient Hospital Settings (§§422.620 and 422.622)

Subpart M Comments and Responses

7. Definitions and General Provisions

8. Grievances

9. Organization Determinations

10. Written Notice

11. Time Frames

12. Expedited Organization/Reconsidered Determinations

13. Authorized Representatives

14. Other Appeal Rights

15. Inpatient Hospital Notice of Discharge

16. Other Comments

N. Medicare Contract Appeals (Subpart N)

O. Intermediate Sanctions (Subpart O)

P. Medicare+Choice MSA Plans

1. Background

2. General Provisions (Subpart A)

3. Eligibility, Election and Enrollment Rules (Subpart B)

a. Eligibility and Enrollment (§422.56)

b. Election (§422.62)

4. Benefits (Subpart C)

a. Basic Benefits Under an M+C MSA Plan (§422.102)

b. Supplemental Benefits (§§422.102 and 422.103)

5. Quality Assurance (Subpart D)

6. Relationships with Providers (Subpart E)

7. Payments Under MSA Plans (Subpart F)

8. Premiums (Subpart G)

9. Other M+C Requirements

10. Responses to Comments

Q. M+C Private Fee-for-Service Plans

1. Background and General Comments (§422.4(a)(3))

2. Beneficiary Issues

3. Provider Payment Issues

4. Noncontracting Provider

5. Quality Assurance (§§422.152 and 422.154)

6. Access to Services (§422.214)

7. Physician Incentive Plans (§§422.208)

I. Background

A. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted August 5, 1997, added sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as the "Medicare+Choice (M+C) Program." (The previous Part C of the statute, which included provisions in section 1876 of the Act governing existing Medicare health maintenance organization (HMO) contracts, was redesignated as Part D.) Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Part B, except for individuals with end-stage renal disease, may elect to receive benefits through either the existing Medicare

fee-for-service program ("Original Medicare") or a Part C M+C plan, if one is offered where he or she lives.

As its name implies, the primary goal of the M+C program is to provide Medicare beneficiaries with a wider range of health plan choices through which to obtain their Medicare benefits. The M+C statute authorizes a variety of private health plan options for beneficiaries, including both the traditional managed care plans (such as those offered by HMOs) that traditionally have been offered under section 1876 of the Act, and new options that were not previously authorized. Specifically, section 1851(a)(2) of the Act describes three types of M+C plans authorized under Part C:

- M+C coordinated care plans, including HMO plans (with or without point of service options), provider-sponsored organization (PSO) plans, and preferred provider organization (PPO) plans.
- M+C medical savings account (MSA) plans (that is, combinations of a high-deductible M+C health insurance plan and a contribution to an M+C MSA).
- M+C private fee-for-service plans.

An entity contracting with us to offer any of the above plans to Medicare beneficiaries is called an "M+C organization."

In addition to expanding the types of health plans that can be offered to Medicare beneficiaries, the M+C program introduces

several other fundamental changes to the managed care component of the Medicare program. These changes include:

- Establishment of an expanded array of quality assurance standards and other consumer protection requirements;
- Introduction of an annual coordinated enrollment period, in conjunction with the distribution by us of uniform, comprehensive information about M+C plans that is needed to promote informed choices by beneficiaries;
- Revisions in the way we calculate payment rates to M+C organizations that will narrow the range of payment variation across the country and increase incentives for organizations to offer M+C plans in diverse geographic areas; and
- Establishment of requirements concerning provider participation procedures.

B. Overview of M+C Regulations

1. Interim Final Rule

On June 26, 1998, we published in the **Federal Register** a comprehensive interim final rule (63 FR 34968) to implement the provisions of section 4001 of the BBA that established the M+C program. That interim final rule set forth the new M+C regulations in 42 CFR Part 422--Medicare+Choice Program. The major subjects covered in each subpart of part 422 are as follows:

- Subpart A--Definitions, including definitions of types of plans, application process, and user fees.
- Subpart B--Requirements concerning beneficiary eligibility, election, enrollment and disenrollment procedures, and plan information and marketing materials.
- Subpart C--Requirements concerning benefits, point of service options, access to services (including rules on enrollee assessments and notification upon termination of specialists), and others.
- Subpart D--Quality assurance standards, external review, and deeming of accredited organizations.
- Subpart E--Provider participation rules and the prohibition against interference with health care professionals' advice to enrollees.
- Subpart F--Payment methodology for M+C organizations, risk adjustment, and encounter data requirements.
- Subpart G--Requirements concerning premiums, cost-sharing, and determination of adjusted community rate.
- Subpart H--Requirements concerning PSOs.
- Subpart I--Organization compliance with State law and preemption by Federal law.
- Subpart K--Contract requirements.
- Subpart L--Change of ownership rules.

• Subpart M--Beneficiary grievances, organization determinations, and appeals.

• Subpart N--Contractor appeals of nonrenewals or terminations of contracts.

• Subpart O--Procedures for imposing intermediate sanctions.

2. Correction Notice

On October 1, 1998, we issued a correction notice in the **Federal Register** (63 FR 52610) to correct technical errors that appeared in the interim final rule. All references in this document to regulation text are to the corrected text unless otherwise noted.

3. February 17, 1999 Final Rule

Additionally, on February 17, 1999, we published a final rule in the **Federal Register** (64 FR 7968) that set forth limited changes to the M+C regulations published in the June 26, 1998 interim final rule. It specifically addressed only a limited number of issues raised by commenters on the June 26, 1998 interim final rule. We indicated in the preamble to the February 17, 1999 final rule that we intended to address all other issues raised by commenters on the M+C interim final rule in a comprehensive M+C final rule to be published at a later date.

The types of comments we addressed in the February final rule are discussed in more detail in section II.A.2.

C. M+C Provisions of the Balanced Budget Refinement Act of 1999

On November 29, 1999, as we were completing the development of this final rule, the Balanced Budget Refinement Act of 1999 (Pub. L. 106-113) (BBRA) was enacted. The BBRA includes a number of provisions that affect the M+C program, and these provisions have necessitated a number of corresponding changes so that the changes in the law made by the BBRA are reflected in the text of the M+C regulations. For the most part, the statutory changes are self-explanatory, and have already taken effect. As noted above, we are accepting public comment on conforming changes to the M+C regulations made as a result of the BBRA provisions. We are revising the regulations to reflect the provisions of the BBRA as follows:

1. Changes in M+C Enrollment Rules (Section 501 of the BBRA)

a. Enrollment in Alternative M+C Plans and Medigap Coverage After Involuntary Terminations

Section 1851(e)(4) of the Act establishes special election periods during which M+C-eligible individuals may disenroll from an M+C plan or elect another M+C plan, including a special election period when an M+C organization or we have terminated a plan or the organization has otherwise discontinued providing the plan in the area in which the individual resides. Section

501(a)(1) of the BBRA revised section 1851(e)(4) to specify that this special election period now becomes available either upon termination or discontinuation or when the organization "has notified the individual of an impending termination or discontinuation of such a plan." We have revised §422.62(b)(1) to reflect this earlier opportunity for an affected enrollee to elect an alternative M+C plan or return to original Medicare. We note that section 501(b) of the BBRA set forth conforming amendments to section 1882(s)(3) of the Act (concerning beneficiary rights to guaranteed issue of a Medicare supplemental policy, that is, a Medigap policy) to allow an individual guaranteed issue rights to a Medigap policy within 63 days of an organization's notification of an impending termination or service area reduction.

b. Open Enrollment for Institutionalized Individuals (Section 501(b))

Section 1851(e) of the Act establishes the time frames, or election periods, for making or changing elections. Section 501(b) of the BBRA amended section 1851(e)(2) of the Act by adding a new subparagraph (D), which provides for continuous open enrollment for institutionalized individuals after 2001. Thus, on or after January 1, 2002 (which represents the first day when limitations are placed on an M+C-eligible individual's enrollment and disenrollment opportunities), M+C-eligible individuals who

are institutionalized, as defined by HCFA, may continue to change from original Medicare to an M+C plan, from an M+C plan to original Medicare, or from one M+C plan to another. We have added §422.62(a)(6) to reflect this provision, with conforming changes at §422.62(a)(4)(i) and §422.62(a)(5)(i). We intend to provide guidance on the meaning of the term "institutionalized" in due time to permit orderly implementation of this change before it takes effect in 2002.

c. Continued Enrollment for Certain M+C Enrollees

Section 1851(b)(1) of the Act establishes the residence requirements for eligibility to elect an M+C plan. Section 501(c) of the BBRA amended section 1851(b)(1) of the Act by adding a new subparagraph (C) to allow an individual to choose to continue enrollment in an M+C plan offered by the organization if (1) the M+C organization eliminates the M+C plan in the service area in which the individual resides and, (2) no other M+C plan is offered in the service area at the time of the elimination of the M+C plan in the service area and, (3) the M+C organization chooses to allow the option to continue enrollment in an M+C plan offered by the organization. If the individual chooses to retain his or her enrollment in the M+C plan, the M+C organization may require that he or she agree to obtain the full range of basic benefits (excluding emergency and urgently needed care) through facilities designated by the organization within the plan’s HCFA-

approved service area. In the case of home health services, since this is a basic benefit that by its nature involves receipt of services in the home, while the provider of the home health services may be located in the service area, actual services would have to be offered in the beneficiary's home. We have reflected this provision in §422.74(b)(3), with a conforming change made in §422.66(e)(2).

2. Change in Effective Date of Elections (Section 502 of the BBRA)

Section 1851(f) of the Act establishes the effective dates for elections and changes to elections made during the various enrollment periods. Prior to enactment of the BBRA, section 1851(f)(2) stated that an election made during an open enrollment period was effective the first day of the following calendar month. Section of the 502 BBRA amended section 1851(f)(2) of the Act to state that an election made during an open enrollment period is effective the first day of the following calendar month, except that if the election or change in election is made after the 10th day of the calendar month, the election is effective the first day of the second calendar month following the date the election or change in election is made. We have revised §422.68(c) to reflect this provision.

3. Extension of Reasonable Cost Contracts (Section 503 of the BBRA)

Section 503 of the BBRA amended section 1876(h)(5)(B) of the Act to permit the extension or renewal of Medicare cost contracts for an additional 2 years, that is, through December 31, 2004. We are revising §417.402(b) to effect this change.

4. Phase-In of New Risk Adjustment Methodology (Section 511 of the BBRA)

Consistent with section 1853(a) of the Act, §422.256 of the M+C regulations provides that M+C capitation payments are adjusted for age, gender, institutional status, and other appropriate factors, including health status, beginning January 1, 2000. In the January 15, 1999, Advance Notice of Methodological Changes for the CY 2000 M+C Payment Rates, we announced the risk adjustment methodology to implement this requirement. One element of the risk adjustment methodology we developed was a transition period during which M+C payments would be based on a blend of payment amounts under the previous system of demographic adjustments and payment amounts based on principal inpatient hospital diagnoses (the PIP-DCG risk adjustment methodology). Under a blend, payment amounts for each enrollee are separately determined using the demographic and risk methodologies, respectively. Those payment amounts are then blended according to the percentages for the transition year. On January 15, 1999, we announced the following transition schedule:

Year	Demographic Method	Risk Method
CY 2000	90 percent	10 percent
CY 2001	70 percent	30 percent
CY 2002	45 percent	55 percent
CY 2003	20 percent	80 percent
CY 2004		100 percent

(Using encounter data from multiple sites of care.)

Section 511(a) of the BBRA revised the original transition schedule for 2000 and 2001 to provide that the blend percentages will be:

Year	Demographic Method	Risk Method
CY 2000	90 percent	10 percent
CY 2001	90 percent	10 percent
CY 2002	at least 80 percent	no more than 20 percent

This provision does not require any changes in the existing M+C regulations, but we have described it here for the convenience of the reader.

5. Encouraging Offering of M+C Plans in Areas Without Plans (Section 512 of the BBRA)

Section 512 of the BBRA amended section 1853 of the Act by adding a new paragraph (i) to provide for "new entry bonus" payments to encourage M+C organizations to offer plans in payment areas (generally, counties) that currently do not have M+C plans

serving the area. Under this provision, which we are incorporating into regulations under §422.250(g), the amount of the monthly payment otherwise made to an M+C organization that offers the first M+C plan in a previously unserved county will be increased by 5 percent for the first 12 months that the plan is offered and by 3 percent for the second 12 months. These bonus payments will be available only for plans that are first offered during the 2-year period beginning January 1, 2000, and only in counties where no M+C plan has been offered, or where any plan offered was no longer offered as of January 1, 2000.

New section 1853(i)(3) specifies that if more than one M+C organization first offers a plan in an uncovered area on the same date, the new entry bonus applies to the payments of both organizations. The BBRA does not expressly address situations in which an M+C organization or organizations begin offering more than one M+C plan simultaneously. Since the bonus is offered to the organization that first offers an M+C plan in an area, or to all organizations that do so on the same date, we interpret this to mean that the bonus would apply to all plans offered by a bonus-eligible organization on the same date. Thus, when an M+C organization offers two M+C plans simultaneously in a previously unserved county, the organization will receive the bonus payment for both plans. Similarly, if two or more M+C organizations

first offer two M+C plans on the same date, each M+C organization will receive the bonus payments for each of its plans. Consistent with section 1853(i)(3) of the Act, the bonus payments are not available to M+C organizations offering a plan in a county that is already partially served by another plan, even if the new plan includes a portion of the payment area not previously covered by an existing plan. As we have stated in OPL 2000.117, a plan is considered to be offered when the sponsoring M+C organization has a contract in effect to serve beneficiaries in the previously unserved area and the plan is open for enrollment.

6. Modification of 5-Year Re-Entry Rule for Contract Terminations (Section 513 of the BBRA)

Section 513(a) of the BBRA amended section 1857(c)(4) of the Act to reduce from 5 to 2 years the period during which an M+C organization that has terminated its M+C contract at the organization's request is barred from re-entering into an M+C contract (absent our finding of special circumstances warranting an exception). Section 513(b)(1) further amended section 1857(c)(4) to provide for a new exception to this general exclusion period if, during the 6-month period after an M+C organization notified us of its intention to terminate an M+C contract, a legislative or regulatory change was adopted that resulted in increased Medicare payment amounts for the given

payment area. In addition, section 513(b)(2) of the BBRA expressly states that the creation of the new exception does not affect our existing authority to grant an exception to this rule where “circumstances which warrant special consideration,” including in the circumstances identified in OPL #103 (OPL 99.103). OPL 99.103 states that we will grant an exception, for example, when an organization proposes to offer a different M+C plan type than it had previously offered, or an organization is proposing to introduce an M+C plan (1) in a geographic area currently served by two or fewer M+C plans, or (2) in an area other than that from which the organization had previously withdrawn when it ended its earlier contract with the Medicare program. We have incorporated the BBRA's revisions to section 1857(c)(4) of the Act into §422.501(b)(5).

7. Flexibility to Tailor Benefits under M+C Plans (Section 515 of the BBRA)

Section 515 of the BBRA amended section 1854 of the Act to permit M+C organizations to elect to apply the premium and benefit provisions of section 1854 of the Act uniformly to separate segments of a service area, provided that the segments are composed of one or more M+C payment areas. This change, which is effective for contract years beginning on or after January 1, 2001, is largely consistent with our existing administrative policy, under which an M+C organization may offer

multiple M+C plans, each with its own HCFA-approved service area, but must offer uniform benefits and premiums within each plan. For a full discussion of the implications of this change, and the conforming changes to the M+C regulations, we refer the reader to section II.C.3 of this preamble.

8. Delay in Deadline for Submission of Adjusted Community Rates (Section 516 of the BBRA)

Section 516 of the BBRA amended section 1854(a)(1) of the Act to delay the annual deadline for submission of adjusted community rate (ACR) proposals and information about enrollment capacity from May 1 to July 1. The statute provides that this change was effective for information submitted by M+C organizations in 1999 for benefits in calendar year 2000, and we are making changes to §§422.60(b)(1), 422.300(b)(2), and 422.306(a)(1) to reflect the new law.

9. Reduction in Adjustment in National Per Capita M+C Growth Percentage for 2002 (Section 517 of the BBRA)

An important element in the methodology used to calculate M+C payment rates involves the determination by the Secretary under section 1853(c)(6) of the Act of a "national per capita M+C growth percentage." Each year, when determining M+C capitation rates, as explained in detail in the June 1998 interim final rule (63 FR 35004), this national growth percentage is applied to the area-specific component of the blended rate and to the minimum

amount, also referred to as the "floor". The national per capita growth percentage is HCFA's estimate of the per capita rate of growth in expenditures. Section 1853(c)(6)(B) of the Act provided that in years from 1998 through 2002, the national per capita M+C growth percentage would be reduced, by 0.8 percentage points in 1998 and 0.5 percentage points in 1999 through 2002. Section 517 of the BBRA amended section 1853(c)(6)(B)(v) of the Act to change the adjustment for 2002 from 0.5 percentage point reduction to a reduction of 0.3 percentage points, and we are revising §422.254(b)(2) to reflect this change.

10. Deeming of M+C Organizations to Meet Requirements (Section 518 of the BBRA)

Section 518 of the BBRA amended section 1852(e)(4) of the Act to set forth several changes related to (1) the process by which an M+C organization can be deemed, based on an accreditation organization's findings, to meet M+C requirements and (2) the standards for which such deeming is permissible. Revised section 1852(e)(4) now includes the following among requirements that must be deemed met if an accreditation body applies and enforces standards at least as stringent as those in this part: those requirements derived from section 1852(b) (concerning antidiscrimination), section 1852(d) (concerning access to services), section 1852(i) (concerning information on advance directives), and section 1852(j) (concerning provider

participation rules), in addition to the requirements under section 1852(e)(1) and (2) concerning an M+C organization's quality assurance program and under 1852(h) concerning the confidentiality and accuracy of enrollee records. We are revising §422.156(b) to add these requirements. In addition, new section 1852(e)(4) specifies that the Secretary must make a determination within 210 days on a private accrediting organization's application to act as an accrediting organization for M+C requirements. This provision in effect mandates the same approval time frame that applies to original Medicare accreditation under section 1865(b) of the Act, and we are incorporating this requirement into §422.158(e).

11. Quality Assurance Requirements for PPO Plans (Section 520 of the BBRA)

Section 520 of the BBRA amended section 1852(e)(2) of the Act to change the quality assurance requirements for PPO plans, effective for contract years beginning on or after January 1, 2000. In the past, PPO plans had been treated under the M+C statute and regulations in the same manner as all other M+C coordinated care plans. New section 1852(e)(2)(D) establishes that, for purposes of the M+C quality assurance requirements, a PPO plan is an M+C plan that (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering

the plan; (2) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization. We are incorporating this definition into the M+C regulations at §422.4. The quality assurance requirements that now will apply for PPO plans are identical to the existing requirements for non-network M+C MSA plans and M+C private fee-for-service plans. Thus, as set forth under revised §422.152, M+C organizations are no longer required to conduct performance improvement projects relative to their PPO plans, or to have their PPO plans meet minimum performance levels. M+C organizations offering PPO plans must still report on standard measures, however, and continue to comply with the quality assessment and performance improvement requirements that apply to all plans, such as those relating to health information and program review. See section II.E of this preamble for further detail on the quality assurance requirements for various types of plans.

12. User Fee for M+C Organizations Based on Number of Enrolled Beneficiaries (Section 522 of the BBRA)

Under section 1857(e)(2) of the Act, the Secretary is directed to collect "user fees" from M+C organizations in order to pay for the costs associated with the enrollment and

information distribution activities required for the M+C program under section 1851 of the Act and for the health insurance counseling and assistance programs under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103-66). Before enactment of the BBRA, the aggregate amount to be collected from all M+C organizations was the lesser of (1) the estimated costs to be incurred by the Secretary in carrying out the applicable information dissemination activities or (2) an amount contingent upon the enactment of appropriations. An individual M+C organization's user fee was equal to its pro rata share of the aggregate amount of fees to be collected from all M+C organizations. Section 522 of the BBRA amended section 1857(e)(2) of the Act to provide that the aggregate amount of user fees to be collected from M+C organizations to carry out the required beneficiary education activities will be based on the lesser of the estimated costs of information dissemination or, for 2001 and thereafter, the “M+C portion” of $100 million, with the M+C portion representing the Secretary's estimate of the ratio of the average number of M+C enrollees for a fiscal year to the average total number of Medicare beneficiaries for the fiscal year. We are revising §422.10 to reflect the new statutory provisions. Consistent with section 522(b) of the BBRA, these changes are effective for user fees charged on or after January 1, 2001, and the Secretary may not increase the user fees for the

3-month period beginning October 2000, above those in effect during the previous 9 months. While we will comply with this latter limitation, we are not including it in regulations text, just as Congress did not include it in the text of section 1857(e).

13. Clarification Regarding Operation of M+C Plans by Religious Fraternal Benefit Societies (Section 523 of the BBRA)

Section 523 of the BBRA amended section 1859(e)(2) of the Act to clarify that a religious fraternal benefit (RFB) society may offer any type of M+C plan, not just an M+C coordinated care plan. We are revising the definition of an RFB plan in §422.2 to reflect this change.

14. Rules Regarding Physician Referrals for M+C Program (Section 524 of the BBRA)

Section 524 of the BBRA amended section 1877(b)(3) of the Act to specify that certain Medicare rules establishing prohibitions on physician referrals do not apply for purposes of M+C organizations offering M+C coordinated care plans, although they do apply for purposes of M+C MSA plans and private fee-for-service plans. As discussed in section II.E.10 of this preamble, this policy was incorporated into §411.355(c)(5) of the Medicare regulations through our June 26, 1998 interim final rule.

II. Analysis of and Responses to Public Comments

A. Overview

1. Comments on June 26, 1998 Interim Final Rule

We received 87 items of correspondence containing hundreds of specific comments on the June 26, 1998 interim final rule. Commenters included managed care organizations and other industry representatives, representatives of physicians and other health care professionals, beneficiary advocacy groups, representatives of hospitals and other providers, insurance companies, States, accrediting and peer review organizations, members of the Congress, and others. Consistent with the scope of the June 26, 1998 rule, most of the comments addressed multiple issues, often in great detail. Listed below are the five areas of the regulation that generated the most concern:

- Access issues, including requirements concerning coordination of care, initial assessments of enrollees' health care needs, timely pre-approval of post-stabilization services, and notification responsibilities when an organization terminates its relationship with a specialist.
- Quality improvement standards.
- Payment rates and service area policy.
- Provider participation rules.
- Beneficiary appeals and grievances.

Among the other issues that generated substantial numbers of comments were:

- Eligibility, election, and enrollment policies.

- Marketing restrictions.
- Risk adjustment methodology and encounter data submission.
- Contractual requirements.
- Preemption of State law by Federal law.
- Deadline for ACR submissions and capacity waivers.

2. Issues in February 17, 1999 Final Rule

In the February 17, 1999 final rule, we attempted to address those issues raised by public commenters where we were convinced that changes were needed and could quickly develop policies necessary to implement the changes. We also included policy clarifications for certain areas in which the material in the interim final rule had been misinterpreted. Also, to the extent possible, we addressed time-sensitive issues, such as those that needed to be resolved before publication of this comprehensive M+C final rule or those that could affect plans or beneficiaries in areas where Medicare risk contractors initially chose not to participate in the M+C program. Some of the specific issues we addressed related to provider participation procedures, beneficiary enrollment options, and several access-related issues, including initial care assessment requirements, notification requirements when specialists are terminated from an M+C plan, and coordination of care requirements.

3. Organization of Final Rule with Comment Period

In this comprehensive M+C final rule with comment period, we address all comments received on the interim final rule that were not addressed in the February 17, 1999 final rule. (As noted above, we are also incorporating changes necessitated by the BBRA, subject to public comment.) For the most part, we will address issues according to the numerical order of the related regulation sections. However, many of the comments raise interrelated issues that involve multiple sections of the regulations. In these cases, we generally address all comments on these issues together, whenever the first relevant section of the regulations arises. Also, we note that all comments on the definitions set forth in §422.2 are addressed in the context of the requirements with which the applicable definitions are associated.

4. General Comments and Subpart A Issues

a. Administrative Procedure Act Issues

We received two comments on various aspects of the M+C rulemaking process, as discussed below.

Comment: A commenter contended that the June 26, 1998 interim final rule did not conform to requirements in the Administrative Procedure Act (APA). First, the commenter alleged that HCFA did not engage in "reasoned decision making" because in certain instances cited by the commenter, the preamble contained "no discussion of. . . factual predicates, no discussion of

alternatives that were evaluated and rejected, and no cost-benefit analysis." The commenter specifically cited requirements for a compliance plan and certifications by executives in connection with this contention. Second, the commenter contended that the regulations should have been subjected to prior notice and comment. The commenter argued that the authority in section 1856(b)(1) to issue interim final regulations only applied to existing standards under section 1876, and that failure to publish the rule by June 1 constituted "a failure to satisfy a condition precedent for issuance of an interim final rule without notice and comment." Finally, the commenter argued that the rule impermissibly provided for compliance with our instructions, contending that this was an attempt to require compliance with instructions that should themselves be subjected to notice and comment.

Another commenter commended us on our success in issuing comprehensive regulations for a complex new program in a short period of time.

Response: The interim final rule includes an extensive preamble that explains the basis and purpose of the regulations, and meets the cited requirements of the APA. We believe that this preamble more than satisfies the requirements in the law for explaining the reasoning behind the decisions we made in the interim final rule. In some cases when we actively considered

alternative approaches and rejected them, we included discussion of this in the interim final rule preamble. For example, in the discussion of grievance procedures (63 FR 35022-35023), we indicated that "we considered" including detailed requirements for M+C organization grievance procedures in the interim final rule, and "we considered requiring certain time frames for addressing grievances." Our reasons for not doing so in that rule were also set out in detail.

We do not believe that the APA--or certain court decisions cited by the commenter--require us to discuss in the preamble every possible alternative that might have been considered to the approaches taken in the rule, but only to explain our reasons for the choices we made. To the extent we have received specific comments advocating alternative approaches, we explain in this final rule why we have not adopted these suggestions, where this is the case.

With respect to the specific requirement that M+C organizations have a plan in place for ensuring compliance with applicable State and Federal laws, we indicated in the preamble that we believe that such a plan was part of the administrative and managerial capabilities that should be in place to carry out the contract and <u>comply with</u> obligations under the contract. Many organizations agree with this conclusion, and had compliance plans in place before this requirement was adopted. We believe

that this is an important component of proper management, like an accountable board of directors. We explained in the preamble that we were establishing this requirement as an M+C standard under our authority in section 1856(b)(1) to establish M+C standards by regulation.

As to the requirement for certifications as to the accuracy of data, we clearly explained in the preamble that we believed that since payments to M+C organizations are based on such data, the submission of the data is part of a "claim" for payment in the amount dictated by the data in question. We further explained that a certification of the accuracy of this information will help ensure accurate data submissions, and assist us and the DHHS Office of Inspector General in anti-fraud activities. We believe this is a clear and logical explanation of reasoned decision making in imposing this requirement.

We disagree with the commenter's contention that we were required to provide prior notice and comment before publishing final regulations. Section 1856(a)(1) gives the Secretary the authority to promulgate regulations establishing the standards that will apply under the M+C program, and that the Secretary is authorized to "promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment." (Emphasis added.) The commenter suggests that this authority only applies to requirements that are based on existing

section 1876 standards. This is incorrect, and is contradicted by other BBA provisions citing this rulemaking authority. The reference to section 1876 merely provides that, "consistent with the requirements of this part" (meaning only to the extent that the BBA does not provide or authorize alternative approaches), "standards established under this subsection shall be based on standards established under section 1876 to carry out analogous provisions of such section." section 1856(b)(2). This provision thus only applies to the extent we determine that doing so would be "consistent with" the new Part C provisions, and only with respect to those provisions in Part C that are "analogous" to a section 1876 standard. Even in this case, the new standards need only be "based on" the 1876 standards, not necessarily identical to such standards.

The commenter's interpretation that section 1856(b)(1) of the Act applies only to the repromulgation of existing 1876 standards is also contradicted by other references in the BBA to this rulemaking authority. For example, section 1876(k)(2), added by section 4002 of the BBA, provides for rules dealing with "grandfathered" Part B only enrollees. Since Part B only enrollees were permitted under section 1876, there were no section 1876 standards addressing the treatment of "grandfathered" enrollees. Yet, section 1876(k)(2) provides that such enrollees may "continue [grandfathered] enrollment in. . .

accordance with regulations described in section 1856(b)(1)." Section 1876(k)(2). This makes clear that the rulemaking authority in section 1856(b)(1) is broader than the commenter contends.

The commenter's contention that we cannot avail ourselves of the interim final rule authority because the rule was not published by June 1, 1998, is illogical. If the Congress authorized interim final regulations because it wanted the rules to be in place by June 1, it would not wish regulations that have already missed this deadline to be delayed further by notice and comment rulemaking. Indeed, the fact that rules were not published by June 1 made the desirability and necessity of issuance in interim final form with an opportunity for public comment all the more urgent.

Finally, with respect to our instructions, we intend only to issue instructions that implement or interpret substantive provisions included in these regulations. To the extent the commenter believes that subsequent instructions are issued that should have been subjected to notice and comment, it can make this argument at that time. The fact that we require compliance with guidance we issue to implement these rules is fully consistent with the APA.

b. Types of M+C Plans (§422.4)

i. M+C Coordinated Care Plans (§422.4(a)(1))

A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the M+C organization to deliver the benefit package approved by us. The network is approved by us to ensure that all applicable requirements are met, including access and availability, service area, and quality. Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care. Coordinated care plans include plans offered by HMOs, PSOs, and PPOs, as well as other types of network plans (except network MSA plans). We received no comments on our definition of coordinated care plan.

ii. Religious and Fraternal Benefit Society Plan

One specific type of M+C plan authorized by the BBA is a religious and fraternal benefit society plan (RFB plan), which is defined in section 1859(e) of the Act. An RFB plan is a new plan that may be offered under the M+C program. In §422.2, an RFB society is defined as an organization that (1) is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act and (2) is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches. As noted above, an

RFB plan was defined in the BBA as a coordinated care plan that is offered by an RFB society. We received two comments regarding RFB plans.

Comment: Two commenters noted that the definition of religious and fraternal benefit (RFB) society found in §422.2 of the regulations would be clearer if the word "benefit" were added to the beginning of this definition.

Response: We agree that the word "benefit" was inadvertently omitted and have added the word "benefit" after the words "religious and fraternal" in that section.

Comment: One commenter asked whether RFB society plans are limited to being a coordinated care plan, or whether an RFB society could also offer a private fee-for-service plan or an MSA plan. A related question asked by the commenter is whether RFB plans can include a point of service (POS) option.

Response: As noted above, under the BBA, a RFB society could only offer a coordinated care plan as a RFB plan. Section 523 of the BBRA, however, amended section 1859(e)(2) of the Act to provide that an RFB society may offer any type of M+C plan. An RFB plan that operates as an M+C coordinated care plan may include a POS option, as could any other M+C coordinated care plan.

iii. M+C MSA Plans (§422.4(a)(2))

The comments received regarding M+C MSA plans are discussed in section III of this preamble.

iv. Multiple Plans (§422.4(b))

In the interim final rule, we specified that under its contract, an M+C organization may offer multiple plans, regardless of type, provided that the M+C organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO offering a coordinated care plan, has received from us a waiver of the State licensing requirement).

Comment: Noting that an M+C organization can offer multiple plans under a single contract with us, a commenter asked how multiple plans would work, and whether each would be required to have a separate health services delivery system. The commenter stated that in order to reduce the administrative cost of multiple plans, we should maximize assessment of compliance with Medicare requirements at the M+C organization level and minimize compliance assessment at the individual plan level.

Response: An M+C organization may offer multiple M+C plans under a single contract with us. Each M+C plan must have its own HCFA-approved service area, and a separate ACR submission that also must be approved by us. For coordinated care and network MSA plans, we will verify that each plan has a health care provider network under contract that meets M+C standards for

access and availability to health care services for beneficiaries who enroll in the given plan. Although we will attempt to achieve all appropriate monitoring efficiencies when contractual elements are identical across plans, we have a responsibility to ensure compliance at the plan level when requirements are plan-specific, such as those noted above.

c. Application Requirements and Procedures (§§422.6 and 422.8)

These sections set forth application requirements for entities that seek a contract as an M+C organization offering an M+C plan. One of the new requirements we set forth in the interim final rule was that organizations wishing to contract with us must submit documentation of their appropriate State licensure, or submit documentation of State certification that the entity is, in fact, able to offer health insurance or health benefits coverage meeting State fiscal solvency standards and is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health care services. We further specified that entities meeting the definition of a PSO can be exempted from this requirement if they meet conditions for a waiver, which can be granted by us in accordance with subpart H of part 422. Section 422.8 of the interim final rule describes the application requirements for entities seeking to contract with us to offer M+C plans, as well as our application evaluation procedures.

Comment: One commenter suggested that our use of terms referring to entities that qualify for M+C contracts (M+C organization) and applicants for such contracts are inconsistent and confusing. For instance, at §§422.8(a)(3), 422.8(e), and 422.8(g), we use the term "entity" to refer to an organization applying to become an M+C organization, while at §§422.8(d) and (f) we use the term "M+C organization."

Response: Clearly, we should not refer to an organization that has not obtained approval from us to become a contractor under the M+C program as an "M+C organization." Accordingly, we have revised §422.8 to uniformly refer to organizations that apply to become M+C organizations as "contract applicants." This is consistent with our use of this term elsewhere in this final rule.

We likewise agree with the comment that organizations that have received approval to operate as an M+C organization should uniformly be called an "M+C organization." Accordingly, we have revised applicable subsections of §422.8 to uniformly use the term "M+C organization" to refer to an existing contractor under the Medicare +Choice program.

d. User Fees (§422.10)

This section implements section 1857(e)(2) of the Act, as revised by section 522 of the BBRA. Section 1857(e)(2) requires that M+C organizations share in costs associated with beneficiary

enrollment in M+C plans, including the costs of providing information and counseling on plan choices. It sets forth the maximum amount of the aggregate "user fees" that can be collected from M+C organizations as well as the procedures that we follow to assess and collect these amounts from M+C organizations.

In the June 26, 1998 interim final rule, we referred to interim final regulations published on December 2, 1997, which implemented section 1857(e)(2) for risk contractors under section 1876. (Under section 1876(k)(4)(D), the obligation under section 1857(e)(2) applied to section 1876 contractors in 1998.) These December 1997 interim final regulations set forth a methodology for determining an individual organization's "pro rata share" of the beneficiary costs to be assessed (62 FR 63669). We also explained in the June 26, 1998 interim final rule that we were simply adopting at §422.10, for purposes of the M+C program, the user fee provisions previously set forth in §417.472(h) of the December 1997 interim final rule. As we indicated in the June 26, 1998 interim final rule, we are addressing the comments received on the substance of the December 1997 interim final rule in this comprehensive M+C final rule. (Since there are no remaining section 1876 risk contractors, §417.472(h) itself no longer has any applicability.)

As described above, section 522 of the BBRA subsequently amended the user fee provisions set forth in section 1857(e)(2)

of the Act, effective for user fees charged on or after January 1, 2001. Revised section 1857(e)(2) now establishes that beginning in the year 2001 the maximum amount of aggregate user fees that we may collect during a fiscal year from M+C organizations will be determined by the percentage of Medicare enrollees in M+C plans. Specifically, we will calculate: the annual average number of Medicare beneficiaries enrolled in M+C plans during a fiscal year divided by the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year. This ratio will be multiplied by $100,000,000 to determine the maximum aggregate user fees we may collect from all M+C organizations in a given fiscal year. (Under section 1857(e)(2), we collect the lesser of (1) the actual costs of carrying out the required information dissemination activities or (2) the maximum aggregate amount permitted under the Act.)

We received five letters of comment regarding the interim final rule of December 2, 1997, which established the assessment method under which all M+C organizations are assessed the same fixed percentage of their total monthly Medicare payments, in order to collect the M+C user fee. Two commenters supported the user fee assessment methodology selected by us and considered that it was equitable both to organizations and beneficiaries; three commenters opposed the methodology. We also received six

letters commenting on the same methodology in response to the interim final M+C regulation of June 26, 1998. Again, three commenters argued that the user fee was unfair to M+C organizations since it resulted in these organizations funding an information campaign for all Medicare beneficiaries, not just those enrolled in M+C organizations. These latter concerns are now moot in light of the BBRA amendments limiting M+C user fees to the percentage of information dissemination costs representing the percentage of total Medicare beneficiaries that are M+C enrollees. Comments that remain relevant are discussed below.

Comment: A commenter expressed concern about the costs of the education campaign implemented by us and how the funds collected from M+C organizations would be spent. The commenter asked that we make available detailed information on the budget, resource allocation, and past and projected expenditures for the beneficiary information campaign, in order to justify the user fee funding levels. The commenter also expressed concern that we should not collect more in user fees than entitled by law. Specifically, the commenter noted that at §422.10(d), we are only entitled to collect the lesser of the estimated costs necessary to implement educational activities in that fiscal year or the appropriated amount. The commenter also stated that the reduction in M+C payments due to the assessment of the user fee will deter new organizations from entering the M+C program.

Response: Although not required under the statute or the BBA, we provide an annual report to the Congress that includes an assessment of the implementation of the M+C program. This report also provides budgetary information on the expenditures of the fees we have collected to fund the M+C information campaign. As stated in revised §422.10(d)(2), beginning in fiscal year 2001, we will collect in a fiscal year the lesser of either the amount needed to implement the required information dissemination and other activities, or the amount equal to the M+C portion of $100 million. The fees collected from any one organization would represent a very small percentage of the total annual Medicare payments to that organization, and we do not believe that they would deter an organization from entering the M+C program.

Comment: A commenter argued that the assessment method adopted by us, under which a percentage of the monthly payment to an M+C organization is assessed, is unfair because it results in organizations in high capitation payment areas paying more (in total dollars) than organizations in lower payment areas. The commenter expressed the view that it is unfair to charge an organization in New York more than an organization in Nebraska.

Response: In selecting an assessment methodology, we sought an approach that is as financially equitable as possible regardless of an M+C organization’s size or geographical location. We also wanted a methodology that would not present a

barrier to participation for smaller and new M+C organizations. We adopted the percentage of payment approach because it bases each organization's assessment on the total Medicare dollars flowing to that particular organization. Thus, the fee each organization pays is directly proportional to the total dollars the organization receives from the Medicare program. M+C organizations that receive larger payments (based on monthly enrollment and payment levels) will pay more in total dollars than M+C organizations with less Medicare money coming in.

Comment: A commenter stated that the assessment of a user fee should be directly related to the costs of providing services. Since no evidence has been presented that the costs of a national mail campaign are higher in one county than another, the user fee should be even across all counties.

Response: While the fees collected from M+C organizations will be used primarily to fund a national information campaign designed to reach all Medicare beneficiaries, some funds will go to local efforts, where, as noted above, costs do vary. In any event, this assessment is not an organization-specific "user fee" such as those imposed under the user fee statute. The assessments are not based on specific costs associated with an individual M+C organization, but on a share of aggregate costs. Specifically, the statute provides for each M+C organization to pay its pro rata share "as determined by the Secretary" of the

"aggregate amount" spent on the specified costs. Thus, data on actual costs associated with an individual organization are not relevant. Rather, we consider the fee as an assessment to be levied in a manner that, to the extent possible, equitably balances the financial impact on all organizations.

Comment: A commenter stated that we should not use the user fee assessment as a way to equalize Medicare managed care payments in different areas of the country. Noting that the Congress has provided for a minimum update in high payment areas, the commenter contended that we will be violating the spirit of the law by taking more from organizations offering M+C plans in these areas.

Response: No consideration was given to using the user fee assessment methodology as a tool to adjust the level of Medicare payment to M+C organizations in different parts of the country. In fact, since the percentage impact on all M+C Medicare payments is equal (a fixed percentage of total payment), this is the one approach that maintains the relative payment levels of all organizations.

Comment: Another commenter asserted that the user fee assessment method we selected--with fees based on percentage of an organization’s M+C payment--has the effect of penalizing those M+C plan enrollees who reside in counties with higher payment

rates. The commenter wrote that enrollees in high payment rate areas will pay much more for their existing benefits.

Response: In terms of total dollars, it is true that M+C organizations in high payment areas will pay more on a per member basis than organizations in lower payment areas. However, as previously noted, the assessment percentage is the same for all organizations. A method that does not take into account the total dollars flowing to each plan would be regressive and unfair, because it would have a disproportionately high financial impact on organizations (and their members) located in mid to lower payment areas and those with low enrollment.

Comment: One commenter recommended that all M+C organizations pay a minimum user fee amount and then, on top of that minimum amount, organizations should also pay a flat monthly amount for each member. The commenter stated that this approach would ensure that the user fee is reasonably related to the benefit that the organization will receive from the M+C program.

Response: We considered the approach suggested by the commenter but rejected it because, unless the flat fee were set at a very low level, it would present an entry barrier for organizations with relatively low enrollment levels. We also rejected a flat per member monthly assessment because it does not adjust for the geographic variation in our monthly capitation payments to M+C organizations.